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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. STF, LLC, an organization; STATE OF CALIFORNIA ex rel. STF, LLC, an organization,

Plaintiff,

v.

VIBRANT AMERICA, LLC, A Delaware limited liability company,

Defendant.

Case No. 3:16-cv-02487-JCS

DEFENDANT VIBRANT AMERICA, LLC'S REPLY IN SUPPORT OF MOTION TO DISMISS COMPLAINT

Supporting Documents
1. Request for Judicial Notice

Date: July 24, 2020
Time: 9:30 AM
Courtroom: F
Before the Honorable Joseph C. Spero

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I. INTRODUCTION[1]

Relator STF, LLC admits one of its two members, Chris Riedel, is a serial litigant who has slung similar allegations against clinical laboratories across the United States, *see* Opp. at 25:4-9, including at least one other lawsuit he has brought as Relator STF, a fact Relator seeks to obscure by omitting the Relator's name from the case title *United States ex rel. STF v. Crescendo Biosciences,* No. 16-cv-02043-TSH, 2020 WL 2614959 (N.D. Cal. May 23, 2020). It may be that laboratory specimen processing and collection fees, and patient payment collection practices, can be misused, but that does not entitle Relator to a fishing expedition to challenge these otherwise legitimate practices by laboratories across the country as to which Relator lacks detail and knowledge, with Relator hoping to happen across a liable defendant. This Court should not permit Relator to continue to repackage old allegations against new defendants who have done no wrong. Relator's Complaint lacks sufficient 9(b) detail because Relator does not have detailed information to support its meritless accusations against Vibrant. Dismissal with prejudice is appropriate.

II. DISCUSSION

A. Relator's Theories Do Not Allege Bribes and Cannot Survive Pleading Standards.

Relator fails to plead an AKS violation for either of its alleged FCA theories. Thus, that AKS violations may give rise to an FCA violation, *see* Opp. at 7:1, is inconsequential because the root behavior of an AKS violation—remuneration to induce referrals for the furnishing of services reimbursed by a federal health care program—has not been alleged. Moreover, whether Relator has sufficiently alleged conduct that would constitute an AKS violation is of course appropriate to consider on a motion to dismiss, contrary to Relator's suggestion, *see* Opp. at 12:10-11. Here, Relator has tried to align this case with inapposite cases to bolster its claims that the allegations in the Complaint sufficiently allege a bribe when they in fact do not. Relator relies extensively on three cases—one brought directly by Relator (*Crescendo*) and two brought by Relator-Riedel (*United States ex rel. Riedel v. Boston Heart Diagnostics* and *United States ex rel. Lutz v. Berkeley Heartlab*). As discussed herein, the allegations in those cases contained

[1] "Vibrant," "Relator," "AKS," "FCA," "CFCA," "IFPA," "FMV," and "OIG" are defined in Vibrant's Motion to Dismiss ("Motion to Dismiss," Dkt. 58, cited as "MTD"). Vibrant's Request for Judicial Notice In Support of its Motion to Dismiss, Dkt. 59, is cited herein as "RJN ISO MTD." Relator's Opposition to Vibrant's Motion to Dismiss ("Relator's Opposition," Dkt. 62) is cited herein as "Opp."

greater detail and other crucial dissimilarities to those in this case.[2]

1. Relator Distorts The Applicable Legal Standard.

Relator misstates the legal standard applicable to FCA cases. *See* Opp. at § III. Whereas any complaint must meet Rules 8 and 12(b)(6) to survive a motion to dismiss, when alleging fraud, a complaint must meet the more demanding standard of Rule 9(b) as well.[3] *See* MTD §§ IV, V.B. Relator selectively chooses quotes from *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016), in an attempt to convince the Court that the Rule 9(b) standard is lenient. It is not. Relator conveniently omits from its Opposition the Ninth Circuit's charge in *Swoben* that a "plaintiff must allege the who, what, when, where, and how of the misconduct charged . . . including what is false or misleading about a statement, and why it is false" as well as the Ninth Circuit's clear statements that "conclusory allegations of fraud are insufficient" and "[b]road allegations that include no particularized supporting detail do not suffice." *Swoben.* at 1180 (citations omitted). Moreover, in concluding certain allegations in the *Swoben* complaint *failed* to meet Rule 9(b), the Ninth Circuit explained that although the "allegations may be sufficient to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged . . . they are insufficient to show the allegations against these defendants have a factual basis." *Id.* at 1182 (citations omitted). In *Swoben*, the Ninth Circuit found allegations against certain defendants satisfied Rule 9(b) where the complaint named individual employees of defendants that engaged in the alleged scheme, explained in detail who made false templates, stated when and how fraudulent schemes were formed, identified specific providers, and disclosed how often false claims were paid and the total amount of false claims paid, among other details. *See id.* at 1181-82. By contrast, the court found allegations against other defendants to be deficient that are more similar to the bare allegations here. *See id.* (broad references to time period; generalized identification of "coders" and "patients" without individual identification; conclusory statements regarding how the scheme worked, etc.). As detailed in Vibrant's Motion to Dismiss § V.B, and supported by *Swoben*, Relator fails to meet Rule 9(b).

[2] Relator also cites settlements and a verdict form from the *Berkeley Heartlab* case, *see* Opp. at 1:17-21, which are distinguishable for the same reasons. Moreover, the settlements contained no admissions of liability, and the verdict was not against a laboratory. *See United States v. Blue Wave Healthcare Consultants, et al.*, No. 9:14-230-RMG (D.S.C. 2018), Dkts. 588-1, 588-2, 870.

[3] Relator's citations to cases to bolster its "plausibility standard" argument are not fraud cases and thus are irrelevant. *See Starr v. Baca*, 652 F.3d 1202 (9th Cir. 2011) (section 1983 action); *see In re Auto. Parts Antitrust Litig.* No. 12-md-02311, 2014 WL 840272 (E.D. Mich. Mar. 4, 2014) (antitrust action).

Contrary to Relator's argument, the Ninth Circuit has declined to relax Rule 9(b) as applied to FCA cases.[4] *See United States ex rel. Ebeid v. Lungwitz*, 616 F. 3d 993, 999 (9th Cir. 2010) (declining to relax the pleading standards under Rule 9(b) where plaintiff alleged billing information was solely in defendant's possession; "To jettison the particularity requirement simply because it would facilitate a claim by an outsider is hardly grounds for overriding the general rule, especially because the FCA is geared primarily to encourage insiders to disclose information necessary to prevent fraud on the government"); *see also United States ex rel. Regan v. Carolina Liquids Chemistries, Corp.*, No. 13-cv-01497-JST, 2019 WL 3207851, at *8 (N.D. Cal. July 16, 2019) ("the Ninth Circuit has declined to expand [relaxed pleading standards] to the FCA"); *see United States v. Safran Grp.*, No. 15-CV-00746-LHK, 2017 WL 235197, at *6 (N.D. Cal. Jan. 19, 2017) ("the Ninth Circuit has specified that the requirements of Rule 9(b)—the who, what, where, when, and how—have not been relaxed when analyzing claims made pursuant to the FCA") (citing *Ebeid* at 999). Moreover, if by "relax" Rule 9(b) Relator simply means that it need not identify actual claims Vibrant submitted by payment, Vibrant has already explained that is not required in every case, but that Relator still must allege (and has not alleged) "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ebeid*, 616 F.3d at 998-99 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)); MTD at 9:22-10:8; *see generally* MTD § V.B.

Relator's claim that the FCA and CFCA should be liberally construed, *see* Opp. at 5:12-13, is a non-sequitur. The cases Relator cites relate to what *conduct* is covered by the FCA and CFCA, not a lightened application of pleading standards. *See United States ex rel. Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1049 (9th Cir. 2012) (considering whether FCA liability may be premised on false cost estimates); *City of Pomona v. Superior Court,* 89 Cal. App. 4th 793 (2001) (considering whether CFCA liability may be premised on false statements in sales materials). Vibrant acknowledges that FCA liability

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[4] Relator cites to *Wool v. Tandem Computers, Inc.*, 818 F.2d 1433 (9th Cir. 1987) to support its claim that Rule 9(b) should be relaxed; however, that case did not allege violations of the FCA and instead alleged violations of the securities laws. The Ninth Circuit has occasionally permitted a relaxed pleading standard in the securities context. The other case Relator cites, the unreported *United States ex rel. Vatan v. QTC Med. Servs.*, Inc., 721 F. App'x 662 (9th Cir. 2018), did not relax 9(b) as it related to pleading particular claim submission, but as it related to pleading the terms of a contract between defendant and a third party that formed the basis of relator's FCA claim and where the contract was in the "exclusive possession and control" of defendant. Here, Relator attaches contracts to the Complaint, and they undermine the Complaint's allegations. *See* MTD at 4:25-5:12, 7:6-16.

may arise where an AKS violation has occurred—but that is not in dispute.

2. Phlebotomist Payment Amount Theory Cannot Survive.

a) Relator's FMV allegations do not save its theory.

The Complaint's allegation that the fee Vibrant paid its phlebotomists was not FMV is conclusory and should not be accepted as true. The Ninth Circuit has squarely addressed this question. In *Eclectic Props. East, LLC v. Marcus & Millichap Co.*, the Ninth Circuit affirmed dismissal of the complaint, holding, "we decline to accept the conclusory assertions of [fair market] values as facts." 751 F.3d 990, 999 (9th Cir. 2014). In Vibrant's Motion to Dismiss, Vibrant noted that the $15 fee it paid its phlebotomists was FMV, and cited as support: an exhibit to the Complaint; the greater-than-$15 average amount billed by providers to Medicare for routine venipuncture; and, the $23.46 to $25.46 fee Medicare pays laboratories for certain specimen collection for COVID-19 diagnostic testing.[5] MTD at 5:1-11. The FMV nature of Vibrant's payments undermines the plausibility of those payments being an inducement for referrals. Vibrant's argument is different from the rejected argument in *Crescendo* that a FMV fee can *never* be an inducement under the AKS. *See* 2020 WL 2614959, at *7. Rather, the lack of FMV would not be outcome determinative if there were other, sufficient allegations to support inducement. However, there are no such other allegations here. *See* MTD at 6:6-28-7:18; 12:8-22.[6]

[5] That Vibrant's fee paid to its phlebotomists was between Medicare's $3 payment for a routine venipuncture and Medicare's $23.46 to $25.46 payment for certain COVID specimen collections is not outcome determinative, but it helps frame and contextualize Vibrant's payments. To be sure, what Medicare pays in reimbursement is not an indicator of FMV nor other "fair value," contrary to Relator's suggestion. See Opp. at 9, n.9; *see also Fact Sheet: Medicare Inflation Adjustment*, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, *available at* https://www.acep.org/globalassets/uploads/uploaded-files/acep/advocacy/state-issues/medicare-versus-inflation.pdf (last accessed June 25, 2020) ("[u]tilizing Medicare rates as a standard for determining fair payment for out of network providers is a fundamentally flawed approach because Medicare rates were never designed to represent the fair market value of healthcare services or to even cover provider costs.") *see* Request for Judicial Notice ("RJN"), Ex. A. Further, the rates Medicare pays are often far below the rates commercial insurers pay and are set by legislation, not by arms-length transaction, and thus do not reflect true FMV for an item or service. *See generally* 42 C.F.R. § 411.351 (defining "fair market value"); *see also Why have Medicare costs grown so much slower than the costs of employer-sponsored insurance?*, THE MEDPAC BLOG (Sept. 11, 2017), http://www.medpac.gov/-blog-/why-have-medicare-costs-grown-so-much-slower-than-the-cost-of-employer-sponsored-insurance/2017/09/11/why-have-medicare-costs-grown-so-much-slower-than-the-cost-of-employer-sponsored-insurance ("On average, commercial prices are about 50 percent higher than average hospital costs and are often far more than 50 percent above Medicare payment rates."); *see* RJN, Ex. B.

[6] Further, in *Crescendo*, the court looked to the allegations of inducement related to the deductible cap theory to support inducement as to the phlebotomist payment amount theory. Respectfully, the court should have considered inducement as to each theory separately, and dismissed either theory if lacking in

b) Relator's citations do not help it; payments to phlebotomists for phlebotomy services are meaningfully different.

Vibrant has explained why Relator's reliance on an OIG Advisory Opinion and OIG Special Fraud Alert is misplaced, including due to the crucial distinction that those guidance materials concerned themselves with payments to referring physicians, not to lab-contracted phlebotomists. *See* MTD at 5:12-7:18; RJN ISO MTD, Ex. B-C. Relator's only attempt to respond to Vibrant's explanation is to claim, without support, that payments to independently contracted phlebotomists are worse than payments "directly to physicians." Opp. at 11:3-5. But that cannot be true: physicians order and refer lab tests; phlebotomists cannot. *See* 42 C.F.R. § 410.32(a). And there is nothing nefarious about lab payments to phlebotomists, who provide a necessary service in drawing patient specimens for testing. In order for sophisticated specialty labs like Vibrant to operate out of a single lab with specialized equipment able to accept specimens from distant locations, they must contract with others to collect, package appropriately, and send the specimens to the lab to perform the tests. As a matter of logistics, as well as administrative and patient convenience, it is not uncommon in the industry for a specialty lab to separately contract staff within a physician's office to perform services for the lab while those staff members are not on the clock in the physician's office, particularly where there is not a nearby draw site or mobile phlebotomist who can otherwise perform the services. There is no fraud in that business practice; only Relator's self-serving, unsupported suspicions without basis in detailed factual allegations.

The complaints in the cases Relator relies on to support its theory that payments to phlebotomists were kickbacks, Opp. § IV.A.1, alleged laboratory payments to *physicians*, not separately contracted phlebotomists, and included more detailed allegations than present here. In *Boston Heart*, the complaint alleged multiple "colluding laboratories" directly paid physicians draw fees, including that the labs "encourage[d] physicians to break up their testing needs among" the laboratories so that the physicians could receive "multiple 'packaging' fees per patient, rather than just one fee per patient, regardless of the

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inducement allegations. *See, e.g., United States ex rel. Frazier v. IASIS Healthcare Corp.*, 812 F. Supp. 2d 1008, 1015-19 (D. Ariz. 2011) (reviewing separately plaintiff's eight allegations of doctor/hospital relationships that allegedly violated Stark Act/AKS and dismissing case with prejudice); *United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1218-25 (W.D. Wash. 2011) (denying motion to dismiss with respect to claims that defendant violated AKS through leasing arrangements but dismissing AKS claims based on defendants' alleged provision of free and discounted services to induce referrals).

number of labs to which test specimens [we]re sent." 332 F. Supp. 3d 48, 62. (alteration in original). Moreover, the complaint alleged that, after the 2014 Special Fraud Alert was issued, the defendant lab "began using third parties . . . to funnel the fees to the physicians," specifically identifying by name a lab sales representative who told a physician that "[the Department of Justice] said we can't pay you [the physician] directly, so we pay [a third party], they take some of the money and they pay you. <u>It's all about perception</u>." *Id.* (alteration in original). And, the complaint alleged that defendant lab "sponsor[ed] seminars that discussed how profitable splitting up tests between laboratories can be for physicians . . . ." *Id.* at 74. This is a far cry from the instant case, where the bare allegations are simply that Vibrant paid independently contracting phlebotomists—not referral sources—fees for their services to Vibrant.

There was also an allegation in *Boston Heart* that a specifically-identified sales representative "told the physician that, 'it didn't even matter if [the payee] was a relative as long as the last names were different.'" 332 F. Supp. 3d at 63. (alteration in original). A nearly identical allegation, except attributed to "Vibrant" (not a specific person), appears in the instant case. Compl. ¶ 33 ("VIBRANT recommended to the physician that it be a family member with a different last name, so as not to raise suspicion."). This allegation is deficient, *see* MTD at 11:2-10, and it is an example of Relator repurposing old allegations against a new defendant without knowledge or detail to support such.

Next, in *United States ex rel. Lutz v. Berkeley Heartlab,, Inc.* (hereinafter, *Berkeley Heartlab I*), the complaint alleged specific individual defendants "directly offered the P&H [processing and handling] fees to physicians, talked up the P&H fees, and trained their sales representatives to talk up the P&H fees"; that one defendant, "occasionally approved higher packaging and handling fees on a case-by-case basis to induce physicians to switch to HDL from their competitors" and "authorized the direct payment of some physicians, rather than paying their practices"; and that "Defendants received emails from physicians and attorneys saying that the P&H fees were illegal kickbacks." 225 F. Supp. 3d 487, 496-97. Here, there are no analogous allegations to support the type of detail, especially regarding inducement, the court required in *Berkeley Heartlab I*.

Lastly, while the *Crescendo* case involved a complaint less detailed than *Boston Health* and *Berkeley Heartlab I*, in that case too the allegations described fees paid to *physicians*, 2020 WL 2614959, at *2 , unlike the instant case where there are no allegations of payment to referral sources.

This case is also meaningfully different from instances where a laboratory pays a physician staff member not just for independently contracted services for the lab but also for the staff member's work in the physician's office, which benefit may accrue to the referring physician. Relator admits that the California Public Health Notice upon which it relies relates to a scenario "where a physician's staff member receives simultaneous payment from the physician" and the laboratory. Opp. at 10:24-26; RJN ISO MTD Ex. D. But there are no allegations (much less sufficiently detailed ones) that Vibrant's phlebotomists received payment from the physician's office and Vibrant for the same services or same time period. *See* MTD 7:8-14. And, moreover, Relator fails, and is unable, to address that the exhibits to the Complaint show Vibrant expressly prohibited such practices. *See* MTD 7:8-14.

Relator makes the odd claim in its Opposition that *no* payment from a laboratory to an independently contracted phlebotomist located in a physician's office who provides processing and packaging services to that laboratory is appropriate. *See* Opp. at 9:9-12. There is no such prohibition in the law, nor does Relator cite any. To be sure, physician offices are not paid by Medicare for the services Vibrant's independent phlebotomists perform for Vibrant. Whereas a handling or conveyance of a simple specimen by a physician's office (think a urine sample being carried down the hall to a laboratory) may be bundled into other Medicare payments to the physician's office, that is not considered to be the case for the types of specimens Vibrant phlebotomists package for shipping to and sophisticated testing by specialty labs like Vibrant. It is analogous to a physician referring a patient to an independently-owned lab across town without the physician being expected to cover—or be reimbursed by Medicare for—any associated costs. Relator is taking issue with permissible, industry practice and calling it fraud.

c) Phlebotomist payment amount theory fails to plead the who, what, when, where, and how.

The Complaint fails to allege facts regarding the payment theory with sufficient particularity—the who, what, when, where, and how—that would permit the court to strongly infer that false claims were submitted to the government, including that Relator fails to plead with particularity the elements of an AKS violation—that payments to independent contractor phlebotomists were bribes to induce referrals from physicians. *See* MTD § V.B.1. Relator claims that Vibrant argued Relator needed to detail "every" person, payer, and physician involved, *see* Opp. at 12:15-17, but Vibrant never said this. What Vibrant

did say, and what is the correct standard, is that Relator needs to put forth sufficient detail beyond broad allegations and conclusory statements, *see* MTD at 8:24-9:15. Because Relator fails to supply the necessary detail—not *every* detail—the phlebotomist theory fails Rule 9(b). *See* MTD § V.B.1.

Relator contends that it did satisfy the who, what, when, where, and how and offers irrelevant bullet points. Opp. at 13:9-14:3. Relator simply supplies who, what, when, where, and how for various allegations in its complaint, not the allegations that would support *fraud*, as required. *See United States ex rel. Modglin v. DJO Glob. Inc.*, 114 F. Supp. 3d 993 (C.D. Cal. 2015) ("to satisfy Rule 9(b), a plaintiff must specify the content of the fraudulent representation, the person who made it, when and where the representation was made, and the manner in which it was untrue and misleading, or the circumstances indicating that it was false") (citing *In re GlenFed Securities Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc)). For example, the "when" is not when payments are made to phlebotomists, but when the conversations took place establishing the alleged fraudulent scheme. *See Berkeley Heartlab I*, 225 F. Supp. at 500 (complaint included detailed allegations regarding the time frame of the scheme and when it was established). The "how" is not that monthly logs are kept, Opp. at 13:11-13, but how the alleged scheme works and how *referral sources* received remuneration. *See Crescendo* 2020 WL 2614959, at *8 (finding complaint satisfied Rule 9(b) where allegations detailed *how physicians* directly invoiced the laboratory for referrals). The "where" is not where the monthly log is submitted, but instead where communications took place establishing any alleged scheme. *See Boston Heart,* 332 F. Supp. 3d at 76 (inclusion of physicians' addresses satisfy the where). And, importantly, the "who" is not the signatory to a legitimate business document, but instead who manufactured an alleged scheme (i.e., *which* Vibrant employees) and who received any improper kickbacks (i.e. *which* physicians). *See Modglin*, 114 F. Supp. 3d at 1016 ("[w]here fraud has allegedly been perpetrated by a corporation, a plaintiff must allege the names of the employees or agents who purportedly made the statements or omissions that give rise to the claim, or at a minimum identify them by title and/or job responsibility"); *see also Boston Heart*, 332 F. Supp. 3d. at 61, 76 (numerous employees identified by name and title, other associated labs, and over 50 physicians); *see also Berkeley Heartlab I*, 225 F. Supp. 3d at 496 (identified specific employees and specific physicians). Relator's overbroad, under-detailed, and conclusory attempts to address the who, what, when, where, and how required by Rule 9(b) fails.

Relator ignores most of the case law cited by Vibrant, *see* MTD § V.B.1, and offers a lackluster attempt to distinguish from *United States ex rel. Gough v. Eastwestproto, Inc.*, No. CV-14-465 DMG (SHx), 2018 WL 6929332 (C.D. Cal. Oct. 24, 2018), despite that the deficient allegations in *Gough* were more detailed than those in this case. *See* MTD at 12:8-22. In *Gough*, the relator alleged defendant provided cash and gift cards, and ambulance services at or below costs, in exchange for Medicare transport referrals. The relator attached an email to the complaint wherein a marketing manager for defendant stated doctors' transports were free of charge. *Id*. at *3. In addition, the complaint also included "multiple examples of . . . patients, identified by their initials, that were allegedly transported . . . at no or below cost . . . ." *Id*. Here, the Complaint is less detailed than that in *Gough.* Relator has no factual detail to support its claims of fraud, instead relying on legitimate, redacted business documents[7] and a vaguely-pled communication. This is not sufficient. MTD at 11:2-13; 22:7-10.

Relator also failed to address that *Gough* held FCA allegations rooted in alleged kickbacks must contain sufficient detail that remuneration induced referrals. *See* MTD § B.1.b; *Gough*, 2018 WL 6929332, at *10 ("[w]hile the [complaint] contains sufficient facts to permit the inference that . . . defendants may have intended to offer remuneration to . . . in exchange for Medicare referrals, the complaint does not sufficiently demonstrate that those offers were actually made, that referrals were obtained as a result, or that a false claim was actually submitted in connection with Medicare"). Like in *Gough*, this AKS-based FCA theory should be dismissed. Relator also argues Vibrant "misses the mark" as to Relator's claims of unnecessary testing. Opp. at 15:20. But it is Relator who misses the mark by failing to identify a single claim tainted by an alleged bribe. Relator ignores the extensive case law in the Ninth Circuit requiring relators to plead *why* any test was unnecessary, even where AKS claims are alleged. *See* MTD at 13:1-8.

3. Copayment and Deductible Cap Theory Cannot Survive.

Relator's copayment and deductible cap theory cannot survive because it is not pled with requisite 9(b) particularity. MTD § V.B.2. Relator's first response is that Relator only needs to allege one purpose of the waivers was to induce patient referrals, Opp. at 11:17-19,[8] but that argument fails for at least two

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[7] Unredacted copies of the Complaint exhibits produced in discovery do not reveal sham agreements nor fraud participants (setting aside that discovery is not relevant for assessing the sufficiency of a complaint).

[8] Relator erroneously contends that the test for whether something is remuneration is "whether the

reasons: first, adequately pleading that the purpose of the waivers was a "bad purpose to disobey or disregard the law"—a criminal intent standard as the AKS is a criminal statute—is only one element of many that Relator fails to plead; and second, Relator has not even pled this element. MTD § V.D.

Moreover, Relator otherwise fails to plead this theory. Relator has not sufficiently pled that Vibrant had a policy of capping or waiving patient payments; Relator does not even say which it was nor does Relator respond to Vibrant pointing this out, *see* MTD at 13:15-19. Relator essentially ignores the *Chang* decision, *see* Opp. 16:18, which held that waiving copayments for beneficiaries is not remuneration *to physicians*. *See* MTD 14:20-15:15. Relator does not plead facts supporting copayments or deductibles were capped or waived in order to induce referrals. MTD § V.B.2. Indeed, there are legitimate reasons why a provider may cap copayments or deductibles. *Id*. Moreover, Relator fails to plead any business was actually "pulled through" to Vibrant pursuant to the allegations. *See* MTD § V.B.2.b; *see also Gough*, 2018 WL 6929332 at, at *8 (complaint deficient where relators "merely allege[d] LifeLine's intent to induce more 'off-campus' Medicare transports . . . [but] does not connect 'off-campus' transports actually provided, if any, to Medicare services").

a) The other lawsuits Relator has brought do not help it.

Relator relies on other cases where Relator-Riedel made allegations against other labs. However, each has notable distinctions. In *Crescendo*, the complaint included greater factual detail to support relator's allegations that there was a link—a *quid pro quo,* an inducement—between the waiver of copayments and deductibles and referrals. There, the complaint alleged, "Crescendo informs its salespeople not to include information on the capping and waiving of fees in emails" and that a Crescendo salesperson texted a physician, "I can't put in email our max out of pocket for our test." *Crescendo*, 2020 WL 2614959, at *3. The court found these allegations *necessary* as to alleging both inducement under 9(b) and scienter. *Id.* at *11 (as to 9(b), placing great weight on that "one of Crescendo's salespeople—whom STF identified by name—was asked on April 11, 2016 about patient co-pays and patients inability to pay fees, and that Jacobson responded in a text that she couldn't put in an email that the cap was $25"); *id.* (holding scienter allegations sufficient because they identified specific supporting text messages and

complaint alleged at least one of the purposes of the waiver was to induce patient referrals." Opp. at 11:17-18.

emails). The instant case lacks such details that would support inducement or scienter.

In *Boston Heart*, the complaint alleged Boston Heart "promise[d] physicians that it w[ould] waive the co[-]payment[s] as long as the physicians send all of their lipid-related business—including Medicare business—to [Boston Heart]." 332 F. Supp. 3d at 60.[9] (alteration in original). The court was clear: "this sufficiently provides both the link between Boston Heart and the physicians' referral of Medicare business . . . because the relator specifically alleges that Boston Heart agreed to waive co-payments and deductibles in exchange for physicians referring Medicare patients to Boston Heart—the link is a quid pro quo with the terms of agreement being that Boston Heart would only waive co-payment and deductibles if it received referrals of Medicare patients." *Id.* at 78. In the instant case, there are no allegations Vibrant promised physicians waivers *in exchange for* anything, much less Medicare referrals. *See* MTD at 15:17-22.[10]

Berkeley I fails to help Relator because that court *dismissed* Relator-Riedel's allegations against defendant BlueWave regarding waiver of co-payments and deductibles for private pay beneficiaries for failure to plead with particularity pursuant Rule 9(b). *See* 225 F. Supp. 3d at 506. The claims that did survive the motion to dismiss were intervened allegations that defendants waived TRICARE deductibles, because defendant "cannot, as a matter of law, waive required TRICARE copays and deductibles." *Id.* at 497.[11] *United States ex rel. Lutz v. Berkeley Heartlab, Inc.* (hereinafter, *Berkeley Heartlab II*) is similarly unhelpful because contracts between defendant marketing company, BlueWave, and defendant laboratories "*required* the laboratories to agree not to charge patients for co-payments and deductibles." 247 F. Supp. 3d 734, 731 (emphasis added). BlueWave then used this fact in written pamphlets given to physicians when marketing laboratories' services. *Id.* In addition, BlueWave received payment from defendant laboratories in "excess of $218 million in connection with those referrals." *Id.* In this case, there are no allegations of such requirements or marketing. Relator-Riedel hopes that its successes in

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[9] This same allegation appears in Riedel's *Berkeley Heartlab* case. *United States v. Berkeley Heartlab, Inc*., 225 F. Supp. 3d 487, 506 (D.S.C. 2016) ("Defendants promise physicians that they will not collect co-payments, as long as the physicians send all of their lipid-related business—including Medicare business—to the Defendants' laboratories.").

[10] *See also Chang*, 2017 WL 10544289, at *2 (complaint named a physician who "would not refer patients to [defendant] if these co-payments were not waived").

[11] The government declined to intervene as it related to Relator-Riedel's allegations regarding waiving private-pay beneficiaries' deductibles, presumably because waiving private-pay copayments does not implicate the AKS.

other lawsuits, for which it alleged far greater factual detail, will sway this Court into ruling in its favor, but instead the Court should see through the bare and conclusory allegations in this Complaint and dismiss it with prejudice.

b) Cap theory fails to satisfy the who, what, when, where, and how.

Relator fails to sufficiently detail the requisite who, what, when, where, and how. Most obviously, the "what" Relator claims is conclusory. *See* Opp. at 16:1-3. Nowhere does the Complaint allege any promise from Vibrant in exchange for referrals, *see* MTD at 15:17-22, nor even *what* Vibrant supposedly provided, *see id.* at 13:15-19. Vibrant has already addressed why Relator's attempts at "who," "when," and "how" also fall short. *Cf.* Opp. at 16:1-17:7; MTD at 13:20-14:15. And, Relator's statement that *Georgia ex rel. Hunter Labs v. Lab. Corp. of Am.*, No. 1:13-cv-1838-SCJ, 2015 WL 12591797 (N.D. Ga. May 19, 2015) involved below-cost testing, and not waivers of patient payment obligations, Opp. at 16:8-12, is a distinction of no consequence.[12]

B. <u>The Materiality Standard Applies and Mandates Dismissal.</u>

In response to Vibrant's materiality argument (that provides an independent reason this case should be dismissed, MTD at 16-17), Relator incorrectly responds materiality "only becomes an issue in 'implied certification' cases." Opp. at 20:6-8. But the Ninth Circuit has clearly held otherwise. *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902 (9th Cir. 2017) ("Under all three theories the essential elements of False Claims Act liability are: (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due."). Relator next seeks to distinguish this case from Vibrant's citations because Relator has alleged violations of the AKS here. However, Relator has not pled violations of the AKS, except in unacceptable conclusory terms that do not pass muster under pleading standards. *See* MTD § V.A; *supra* at §§ II.A.2.c; II.A.3. The Complaint fails to plead materiality because there are no allegations to support that the Medicare program would have denied reimbursement on the basis of valid Vibrant payments nor on the basis of alleged caps Vibrant placed on copayments or deductibles for private pay patients. Relator's conclusory

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[12] The MTD cited to *State ex rel. Hunter Labs., LLC v. Quest Diagnostics Inc.*, No. 1:13-cv-01838-SCJ, 2014 WL 12543888 (N.D. Ga. Mar. 14, 2014), 13:22-24, a separate decision than the one cited to by Relator. Opp. at 16:8-12.

AKS allegations do not enable Relator to survive Vibrant's materiality challenge. *See* MTD § V.C.

C. The CFCA Causes of Action Fall with the FCA Causes of Action.

Relator admits its CFCA allegations rise and fall with the FCA allegations. Opp. at 23:1-4; *see also* MTD at 19:7-18. As such, those too should be dismissed with prejudice.

D. Relator Has Neither Standing Nor Requisite Allegations to Support IFPA Claims.

Relator lacks standing for its IFPA causes of action because it is not an "interested person" under the IFPA. Contrary to Relator's argument, Opp. at 24:5-11, just because Relator has obtained documents it attached as exhibits to its Complaint and made other allegations about Vibrant does not establish Relator is an interested person under IFPA. The only court that squarely addressed the meaning of "interested person" under the IFPA held an "interested person" requires "something more than merely being a source of information or standing to gain from any ultimately [sic] recovery." *United States ex rel. Lutz v. Lab. Corp. of Am. Holdings*, No. 9:14-cv-3699-RMG, 2019 WL 236799, at *1 (D.S.C. Jan. 16, 2019). The *Lutz* court carefully analyzed and applied California cases interpreting "interested person" in other contexts to mean "a person having a direct, and not a merely consequential interest in the litigation." *Id.* at *4 (quoting *Associated Boat Indus. of N. Cal. v. Marshall*, 104 Cal.App.2d 21, 22, 230 P.2d 379, 380 (1951)); *see also* MTD at 19:27-20:14. Relator has not pled "direct" interest in this litigation; only the consequential interest in hunting for a bounty. In its Opposition, Relator offers no other definition of "interested person" and instead seeks to align the statutory text "interested person" in the IFPA with the statutory text "a person" in the FCA. *See* Opp. at 23:26-24:4. But as Vibrant has already explained, standing under the IFPA and FCA are meaningfully different. *See* MTD at 20:7, n.8.

Moreover, Relator has not otherwise stated a claim under IFPA. Relator makes no attempt to address Vibrant's arguments and legal citations. *See* Opp. at 24:15-25. Instead, Relator broadly asserts that its conclusory allegations are sufficient and makes statements that bear no relation to Vibrant's arguments. *See id.* (claiming without example or support that Vibrant's IFPA arguments are inappropriately factual and asserting "Relator is not required to allege facts sufficient to eliminate all potential purposes for Defendant's conduct," an argument not made by Vibrant).

E. Dismissal Should Be With Prejudice.

Dismissal should be with prejudice. Relator and its member Riedel are serial litigants, *see, e.g.,*

MTD at 22:27, n.10; Opp. at 1:14-21, n.3, slinging similar allegations (deficiently as to Vibrant) in multiple lawsuits with the hope of happening on a liable defendant. That is not acceptable in any litigation, but most unacceptable for allegations of fraud, where the reputational harm of pending fraud allegations is significantly greater. In other words, this is the exact type of case that should be dismissed under Rule 9(b). *See* MTD § V.G. Relator has not responded to Vibrant's call for dismissal with prejudice, thereby conceding dismissal with prejudice is appropriate should the case be dismissed. *See Lesnik v. Se*, No. 16-CV-1120-LHK, 2018 WL 4700342, at *5 (N.D. Cal. Oct. 1, 2018) (dismissing with prejudice FCA claim given plaintiffs' failure to respond to argument in motion to dismiss) (collecting cases).

II. CONCLUSION

For the foregoing reasons and those discussed in Vibrant's Motion to Dismiss, Vibrant respectfully requests this Court dismiss this case in full and with prejudice.

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